REMARKS

Claims 6-12, 14-19, 38, 41, 44, 45 and 57-73 were pending in the present application. Claims 1-5, 20-37, 39-40, 42-43 and 46-56 were previously withdrawn from further consideration by the Examiner as being drawn to non-elected inventions, and claims 67-69 are newly withdrawn as directed to an invention that is independent or distinct from the invention originally claimed.[1] By virtue of this response, claims 14-17, 41, and 57-58 have been amended, and new claims 74-80 have been added. Accordingly, claims 6-12, 14-19, 38, 41, 44, 45, 57-66, and 70-80 are currently under examination. For the Examiner's convenience, a set of currently pending claims is attached.

The claim amendments and new claims are supported by the specification as follows: Support for amendments to claims 14 and 15 may be found for example on p. 32, lines 11-19. Support for amendments to claims 16 and 17 may be found for example on p. 34, lines 10-15. Support for amendments to claims 57 and 58 may be found for example on p. 57, line 35 - p. 58, line 7. Support for amendments to claims 72 and 73 may be found for example on p. 30, lines 11-30. Support for new claims 74 and 75 may be found for example on p. 30, lines 11-30. Support for new claim 76 may be found for example on p. 53, lines 21-29. Support for new claim 77 may be found for example on p. 4, line 17. Support for new claims 78-80 may be found for example on p. 33, lines 23-24 and lines 28-30, on p. 34, line 10 - p. 36, line 13, and in the Examples.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached pages are captioned "**VERSION WITH MARKINGS TO SHOW CHANGES MADE**".

With respect to any claim amendments or cancellations, Applicants have not dedicated or abandoned any unclaimed subject matter and moreover have not acquiesced to any rejections

[1] Applicants note that the Office Action Summary fails to reflect the withdrawal of claims 67-69 from consideration, but rather, incorrectly lists them as still pending in the application.

and/or objections made by the Patent Office. Applicants expressly reserve the right to pursue prosecution of any presently excluded subject matter or claim embodiments in one or more future continuation and/or divisional application(s).

Applicants have carefully considered the points raised in the Office Action and believe that the Examiner's concerns have been addressed as described herein, thereby placing this case into condition for allowance.

Entry of previous amendments

Applicants respectfully ask for acknowledgment that the amendments of June 22, 2000 and October 3, 2000 have been entered.

Concerning Applicants' previous request for rejoinder of claims

The Examiner denied Applicants' request for rejoinder in the amendment filed on December 4, 1999 (Certificate of Mailing date of November 17, 1999) because Applicants allegedly did not refer to claim numbers in the request. Applicants need not refer to specific claim numbers in order to identify method claims. Applicants note that the Amendment of December 4, 1999 stated, and the Examiner herself noted in the present Office Action (page 2), a request by the Applicants of rejoinder of "presently excluded method claims, to the extent that they incorporate all the limitations of the product claims." An example of such claims may be found in claims 67-69, discussed below, for which Applicants respectfully request rejoinder upon allowance of composition claims.

Election/Restriction Requirement

The Examiner stated that claims 67-69 are withdrawn from consideration as being directed to a non-elected invention because the claims are allegedly drawn to a method of making the polypeptide 11D10 by a recombinant technique which is different from the product claims that are pending in the instant application. Applicants respectfully disagree with the

Examiner's reasoning. Claims 67-69 incorporate all the limitations of the product claims pending in the instant application. Claim 67 recites "the polynucleotide of claim 6." Claim 68 recites "the polynucleotide of claim 72." Claim 69 recites "the polynucleotide of claim 73." As such, upon allowance of composition claims, and under well-established patent practice, these claims should be rejoined. Thus, Applicants respectfully request the rejoinder of these claims.

Priority

The Examiner stated that a priority statement reading "This is a 371 of Application No. PCT/US96/20757, filed December 19, 1996" should be entered following the title of the invention or as the first sentence of the specification. The first sentence of the specification has been amended to contain the requested language, although the language of the specification, as amended on November 17, 1999, conveys this information. Withdrawal of the request to correct the priority statement is respectfully requested.

The Examiner noted that the reference in the amendment filed on October 3, 2000, to the provisional application Serial No. 60/035,345 filing date of January 29, 1996 does not correspond with the filing date recited in the oath/declaration.[2] Applicants note that the January 29, 1996 date corresponding to the filing date of provisional application Serial No. 60/035,345 as stated above is correct. No correction is required.

Oath/Declaration

The Examiner states that the oath or declaration is defective because the filing date of priority application number 60/035,345 is incorrect and does not match the referenced date in the specification. The Office Action, citing MPEP §§ 602.01 and 602.02, states that a new oath or

[2] The Examiner referred to the priority statement in the context of the Amendment filed October 3, 2000, even though this statement was not literally re-iterated in the October 3, 2000 Amendment. This statement was set forth in the June 22, 2000 Amendment (Paper No. 19). Thus, the Examiner has implicitly acknowledged entry of the Amendment of June 22, 2000 (which includes the priority statement).

declaration in compliance with 37 CFR § 1.67(a) identifying the instant application by application number and filing date is required.

Applicants believe that since the originally filed declaration accurately identifies the priority application, it meets the statutory requirements and therefore does not need to be re-executed. Applicants respectfully note that MPEP § 601.01(a), cited by the Examiner, states that "[t]he oath or declaration . . . must identify the specification . . . which is intended to be part of the original disclosure." There is no statement requiring that a date as well as serial number is required. The filed declaration accurately identifies the specification of the priority application by its serial number, 60/035,345. Although there is a clerical inaccuracy in the declaration with respect to the date that this provisional application was filed, *the serial number is unique and can therefore identify only one specification*. Since the serial number was accurately recorded in the declaration, the requirement that the declaration identify the specification which is intended to be part of the original disclosure has been fulfilled.

In view of the foregoing, Applicants respectfully request that the Examiner withdraw the request for a new declaration.

Rejection under 35 U.S.C. § 112, first paragraph

A. Claims 14, 15, 57, 58, and 72-73 stand rejected under 35 U.S.C 112, first paragraph, as allegedly a "scope" rejection.

By this Amendment, claim 14 has been amended to recite "a polynucleotide comprising a region of at least 100 contiguous nucleotides of the sequence contained in SEQ ID NO:1." Claim 15 has been amended to recite "a polynucleotide comprising a region of at least 75 contiguous nucleotides of the sequence contained in SEQ ID NO:3."

As a preliminary matter, Applicants note that the Examiner appears to have misconstrued the claims. The Examiner alleges that claims 14, 15, 57, 58 and 72-73 are drawn to "a polynucleotide comprising of at least 15 nucleotides encoding CDRs of either light chain or heavy chain of SEQUENCE ID NO:2 and 4." Office Action, page 3. First, Applicants note that

claims 14 and 15 are directed to a polynucleotide comprising "a region of at least 15 contiguous nucleotides of the sequence contained in SEQUENCE ID NO:1" and "a region of at least 15 contiguous nucleotides of the sequence contained in SEQUENCE ID NO:3", respectively. The claims do not recite that the polynucleotide comprises at least 15 nucleotides "encoding CDRs of either light chain or heavy chain of SEQUENCE ID NO:2 and 4." Indeed, the only reference to SEQUENCE ID NOs:2 and 4 is in claims 72 and 73, respectively. Second, Applicants note that claims 57 and 58 are directed to kits.

Applicants disagree with the Examiner's contention that the scope of the claims is not commensurate with what is disclosed in the specification. The Examiner alleges that the claims read on all polynucleotide sequences which have at least 15 nucleotides in SEQUENCE ID NO:2 and 4 but does not specifically state which area of the sequence contain the essential 15-mer. Applicants do not understand what the Examiner means by the "essential 15-mer." Based on the Examiner's reference to the phrase "at least 15 nucleotides" and based on the basis set forth by the previous Examiner in the previous rejection, which the present Examiner contends s/he is maintaining, Applicants read the Examiner's rejection as pertaining to claims 14 and 15. As noted above, claims 14 and 15 do not refer to SEQUENCE ID NO:2 or 4, but rather to 1 and 3, respectively. Thus, the Examiner's assertion that the claims "read on all polynucleotide sequences which have at least 15 nucleotides in SEQUENCE ID NO:2 and 4" is clearly inaccurate and unfounded. The scope of these claims is evident from the limitations recited in these claims.

The specification clearly enables and provides adequate written description for the claimed invention. Amended claim 14 is directed to "a polynucleotide comprising a region of at least 100 contiguous nucleotides of the sequence contained in SEQUENCE ID NO:1." Amended claim 15 is directed to "a polynucleotide comprising a region of at least 75 contiguous nucleotides of the sequence contained in SEQUENCE ID NO:3." Methods of preparing polynucleotides are extensively disclosed in the specification at, for example, from page 33, line 21 to page 34, line 6. These polynucleotides can be used in a variety of ways, as described

throughout the specification, for example from page 36, line 31 to page 38, line 9. Written support for amended claims 14 and 15 can be found throughout the specification at, inter alia, page 32, lines 11-19.

The specification also teaches how to make and use the invention claimed in claims 72 and 73. The light chain CDR sequences are provided and clearly indicated in SEQUENCE ID NO:2 and the heavy chain CDR sequences are provided and clearly indicated in SEQUENCE ID NO:4. Based on routine molecular biological techniques and information, one of skill in the art can readily and routinely make a polynucleotide encoding these sequences. These polynucleotides can be used in a variety of ways, as described throughout the specification, for example from page 36, line 31 to page 38, line 9. The claimed invention is amply described in the specification, for example, on page 30, lines 11-30.

Applicants respectfully request that this rejection be withdrawn.

B. Claims 6-12, 16-19, 38, 41, 44, 45, 59-66 and 70-72 are newly rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to provide an adequate written description of the invention and failing to provide an enabling disclosure, because the specification does not provide evidence that the claimed biological materials are (1) known and readily available to the public; (2) reproducible from a written description (e.g. sequenced); or (3) deposited.

Applicants respectfully traverse the rejection because the sequences for the claimed polynucleotides are provided in the specification, as well as amino acid sequences of the variable region of 11D10, thus providing enablement. Such disclosure renders a deposit of the hybridoma producing 11D10 unnecessary. However, without acquiescing to the rejection, and in order to expedite prosecution, Applicants submit herewith a receipt from the American Type Culture Collection, in conformance with the Budapest Treaty, referencing deposit of the murine hybridoma cell line that produces monoclonal antibody 11D10. The ATCC designation for this cell line is HB 12020, as indicated in the specification on p. 8, lines 27-30.

In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, first paragraph.

Rejections under 35 U.S.C. § 102(b)

A. Claims 15 and 58 stand rejected as allegedly being anticipated by Mo et al., Liu et al., DeWaele et al. As amended, claim 15 recites "[a] polynucleotide comprising a region of at least 75 contiguous nucleotides of the sequence contained in SEQ ID NO:3." The sequences disclosed in Mo et al., Liu et al., and DeWaele et al., as evidenced by the computer sequence alignment, do not read on 75 contiguous nucleotides of the sequence disclosed in SEQ ID NO:3. Therefore, these references do not anticipate claims 15 and 58.

In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. § 102(b).

B. Claims 14 and 57 stand rejected under 35 U.S.C. 102(b) as allegedly being anticipated by Shlomchik et al., Kavaler et al, Seidman et al. or Darsley et al. As amended, claim 14 recites "[a] polynucleotide comprising a region of at least 100 contiguous nucleotides of the sequence contained in SEQ ID NO:1." The sequences disclosed in Shlomchik et al., Kavaler et al., Seidman et al., and Darsley et al., as evidenced by the computer sequence alignment, do not read on 100 contiguous nucleotides of the sequence disclosed in SEQ ID NO:3. Therefore, these references do not anticipate claims 14 and 57.

In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. § 102(b).

C. Claims 6-12, 16-19, 38, 41, 44, 45, 59-66 and 70-72 stand rejected as allegedly being anticipated by Chatterjee et al. (Antigen and Antibody Mol. Engineering, 1994, Cancer Immunol. Immunother., 1994) and Chakraborty et al. (Proc. Am, Assoc. Cancer Res., 1994). The Examiner notes that Applicants have declared that to their best knowledge, the 11D10

antibody was not made publicly available before the filing date of the instant application. However, the Examiner alleges that there is evidence to the contrary in the form of the publication policy of *Cancer Research*, requiring authors to make freely available biological materials that were used in the research reported. The Examiner cites Applicant's publication in *Cancer Research*, vol. 55, pp. 1525-30, April 1995 as an anticipating reference under § 102(b). Applicants respectfully traverse this rejection.

Applicants respectfully submit that this reference is an improper § 102(b) reference, since it was published less than one year before the effective filing date of the instant application. The publication date of the reference is April 1, 1995, which is less than one year prior to the effective filing date of the instant application (based on claim of priority back to provisional application no. 60/031,306 (formerly U.S. Serial No. 08/575,762, filed December 20, 1995) and provisional application no. 60/035,345 (formerly U.S. Serial No. 08/591,965, filed January 29, 1996)).

The Examiner also maintains that the publication policy of *Cancer Research* requires that by publishing in the journal, the authors agreed to make their hybridoma and 11D10 antibody freely available. The Examiner states that this policy is contradictory to Applicants' declarations in which Applicants declared that to their best knowledge, the antibody was not made publicly available before the filing date of the instant application. Applicants respectfully submit that the journal merely has a *policy* that authors agree to make freely available to others materials used in reported research, but does not *require* that the authors do so. Nonetheless, as discussed above, this reference is unavailable as § 102(b) art.

Applicants note that this reference was cited and withdrawn as a §102 reference in related application U.S. serial no. 08/766,350, which has the same priority date as the instant application. The roles and contributions of the authors of the Chakraborty et al. reference have been addressed in the Declaration of Malaya Bhattacharya-Chatterjee, a copy of which accompanied the response to the May 17, 1999 Office Action, which is attached for the Examiner's convenience. This declaration shows that the Chakraborty et al. reference is not

available as a §102(a) or §102(f) reference, and as discussed above, it is also not available as a §102(b) reference.

Since the only basis for maintaining this rejection has been removed, the §102 rejection should be withdrawn. Applicants note that previously-cited references Chatterjee et al. (Antigen and Antibody Molecular Engineering 1994), Chatterjee et al. (Cancer Immunol Immunother 1994), Chakraborty et al. (Proc Am Assoc Cancer Res 1994), and Chakraborty et al. (J Immunotherapy Vol 18) are not discussed by the Examiner in this Office Action. Therefore, Applicants assume that the §102(b) rejections based on these references have been withdrawn. However, for completeness, Applicants reiterate the arguments made previously in response to the Office Action dated May 17, 1999, in which Applicants traversed this rejection.

As discussed by Applicants in the May 17, 1999 response, the cited references disclose the 11D10 hybridoma, but do not disclose the sequence encoding the 11D10 antibody. Applicants maintain that disclosure of a the 11D10 hybridoma alone would not enable one skilled in the art to deduce the polynucleotide sequence encoding the heavy or light chain variable regions of 11D10. During prosecution of related application U.S. Ser. No. 08/766,350, Applicants explained why prior publications referencing antibody 11D10, but not disclosing the sequence of 11D10, were insufficient to place the claimed invention into the hands of the public, based on the mechanism of antibody formation. Applicants filed declarations by Malaya (Bhattacharya-) Chatterjee, Kenneth Foon, and Sunil Chatterjee, stating that to the best of their knowledge and belief, neither the 11D10 antibody nor the 11D10 producing hybridoma cell line were made accessible to the public prior to the filing of the application. These declarations were submitted with the response to the May 17, 1999 Office Action and are attached for the Examiner's convenience. Further, as discussed above, the publication policy of *Cancer Research* did not serve to place the 11D10 hybridomas into the hands of the public by virtue of Applicants publishing their research in this journal.

In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection under § 102(b).

Rejections under 35 U.S.C. 102(e)

A. Claims 15 and 58 stand rejected under 35 U.S.C. 102(e) as allegedly being anticipated by Gourlie et al. (US 5,808,033). As amended, claim 15 recites "[a] polynucleotide comprising a region of at least 75 contiguous nucleotides of the sequence contained in SEQ ID NO:3." The sequence disclosed in Gourlie et al., as evidenced by the computer sequence alignment, does not read on 75 contiguous nucleotides of the sequence disclosed in SEQ ID NO:3. Therefore, this reference does not anticipate claims 15 and 58.

In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. § 102(e).

B. Claims 15 and 58 stand rejected under 35 U.S.C. 102(e) as allegedly being anticipated by Bendig et al. (US 5,840,299). As amended, claim 15 recites "[a] polynucleotide comprising a region of at least 75 contiguous nucleotides of the sequence contained in SEQ ID NO:3. The sequence disclosed in Bendig et al., as evidenced by the computer sequence alignment, does not read on 75 contiguous nucleotides of the sequence disclosed in SEQ ID NO:3." Therefore, this reference does not anticipate claims 15 and 58.

In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. § 102(e).

Rejection under 35 U.S.C. § 101

Claims 14, 15, 57, 58 and 72-73 are newly rejected under 35 U.S.C. § 101, allegedly because the claimed invention is directed to non-statutory subject matter. Applicants assume that this rejection is due to an erroneous assumption by the Office that the claimed polynucleotides are naturally-occurring. Applicants note that the polynucleotide sequences of the invention are not naturally-occurring in the sense that they arose due to manipulations to make an antibody-producing hybridoma, which does not occur in nature. Applicants also point out that U.S. Pat. No. 5,934,821, claiming polynucleotides which also arose from production of a hybridoma (see

U.S. Pat. No.5,612,030), does not contain the term "isolated"; nor did the Office raise this rejection in that case.

In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. § 101.

Withdrawal of all previous rejections

The Examiner states that all other rejections previously cited in the Office Action in Paper #15 are withdrawn upon review of Applicant's arguments and amendments to the claims. Applicants acknowledge with appreciation the withdrawal of all other previous rejections, such as the rejections under 35 U.S.C. § 112, second paragraph, to the extent that they have not been reiterated in this Office Action. Applicants would appreciate the Office officially withdrawing these rejections.

CONCLUSION

Applicants have, by way of the amendments and remarks presented herein, removed the issues for the rejections and addressed all issues that were raised in the outstanding Office Action. Accordingly, reconsideration and allowance of the pending claims are respectfully requested. If it is determined that a telephone conversation would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the unlikely event that the fee transmittal is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicants petition for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 304142000322. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

Dated: 10/24, 2001

By: Catherine M. Polizzi

Catherine M. Polizzi
Registration No. 40,130

Morrison & Foerster LLP
755 Page Mill Road
Palo Alto, California 94304-1018
Telephone: (650) 813-5651
Facsimile: (650) 494-0792

VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Specification

The paragraph beginning at page 1, line 6, has been amended as follows:

This application is [in the U.S. National Phase of international application] a §371 of Application No. PCT/US96/20757, filed December 19, 1996, which claims priority to U.S. Serial No. 08/766,350, filed December 13, 1996, which claims the [priority] benefit [to] of provisional application Serial No. 60/035,345, [(]converted from U.S. Serial No. 08/591,965[)], filed January 29, 1996, and also claims the benefit of provisional application Serial No. 60/031,306, converted from U.S. Serial No. 08/575,762, filed December 20, 1995, all of which are incorporated by reference in their entirety.

In the Claims

14. (Twice Amended) A polynucleotide comprising a region of at least [15] 100 contiguous nucleotides of the sequence contained in SEQ ID NO:1[, said region forming a stable duplex with a polynucleotide consisting of the light chain variable encoding sequence of SEQ ID NO:1 under hybridization conditions of 68°C and 0.15M NaCl and 15 mM citrate buffer (1 X SSC)].

15. (Twice Amended) - A polynucleotide comprising a region of at least [15] 75 contiguous nucleotides of the sequence contained in SEQ ID NO:3[, said region forming a stable duplex with a polynucleotide consisting of the heavy chain variable encoding sequence of SEQ ID NO:3 under hybridization conditions of 68°C and 0.15M NaCl and 15 mM citrate buffer (1 X SSC)].

16. (Once Amended) A cloning vector comprising the polynucleotide according to claim 6[, wherein the polynucleotide is a cloning vector].

17. (Once Amended) [A] An expression vector comprising the polynucleotide according to claim 6[, wherein the polynucleotide is an expression vector].

41. (Thrice Amended) An immunogenic composition comprising the polynucleotide of claim 6 [in an amount sufficient to elicit an anti-HMFG immunological response] and a pharmaceutically acceptable excipient.

57. (Once Amended) A kit for detection or quantitation of a polynucleotide comprising a polynucleotide which comprises a sequence encoding a variable region of [monoclonal] antibody 11D10 or a portion thereof, said kit comprising the polynucleotide of claim 14 in suitable packaging.

58. (Once Amended) A kit for detection or quantitation of a polynucleotide comprising a polynucleotide which comprises a sequence encoding a variable region of [monoclonal] antibody 11D10 or a portion thereof, said kit comprising the polynucleotide of claim 15 in suitable packaging.

U.S. Application No. 08/836,455

Title: Murine Monoclonal Anti-Idiotype Antibody 11D10 and Methods of Use Thereof

Inventors: Chatterjee et al.

Filed: 5/9/97

Currently Pending Claims after 10/24/01 Amendment

6. A polynucleotide comprising a sequence encoding a polypeptide that is capable of eliciting an anti-HMFG immunological response in a mammal, wherein the polypeptide comprises an immunoglobulin variable region containing the three light chain complementarity determining regions (CDRs) of antibody 11D10 or an immunoglobulin variable region containing the three heavy chain CDRs of antibody 11D10, wherein antibody 11D10 is produced by the hybridoma deposited under ATCC Accession No. HB-12020 or progeny thereof.

7. A polynucleotide according to claim 6, wherein the polypeptide comprises an immunoglobulin variable region containing the three light chain CDRs of antibody 11D10.

8. A polynucleotide according to claim 6, wherein the polypeptide comprises an immunoglobulin variable region containing the three heavy chain CDRs of antibody 11D10.

9. A polynucleotide according to claim 6, wherein the immunoglobulin variable region is contained in SEQ ID NO:2.

10. A polynucleotide according to claim 6, wherein the immunoglobulin variable region is contained in SEQ ID NO:4.

11. A polynucleotide according to claim 6, wherein the encoding sequence is contained in the variable region encoding sequence in SEQ ID NO:1.

12. A polynucleotide according to claim 6, wherein the encoding sequence is contained in the variable region encoding sequence in SEQ ID NO:3.

14. A polynucleotide comprising a region of at least 100 contiguous nucleotides of the sequence contained in SEQ ID NO:1.

15. A polynucleotide comprising a region of at least 75 contiguous nucleotides of the sequence contained in SEQ ID NO:3.

16. A cloning vector comprising the polynucleotide according to claim 6.

17. An expression vector comprising the polynucleotide according to claim 6.

18. The expression vector of claim 17, wherein the expression vector is vaccinia.

19. A host cell comprising the polynucleotide of claim 6, wherein the polynucleotide is a recombinant polynucleotide.

38. A composition comprising the polynucleotide of claim 6 and a pharmaceutically acceptable excipient.

41. An immunogenic composition comprising the polynucleotide of claim 6 and a pharmaceutically acceptable excipient.

44. The immunogenic composition of claim 41, wherein the polynucleotide is comprised in a live virus or viral expression vector.

45. The immunogenic composition of claim 44, wherein the expression vector is vaccinia.

57. A kit for detection or quantitation of a polynucleotide comprising a polynucleotide which comprises a sequence encoding a variable region of antibody 11D10 or a portion thereof, said kit comprising the polynucleotide of claim 14 in suitable packaging.

58. A kit for detection or quantitation of a polynucleotide comprising a polynucleotide which comprises a sequence encoding a variable region of antibody 11D10 or a portion thereof, said kit comprising the polynucleotide of claim 15 in suitable packaging.

59. The polynucleotide of claim 6, wherein antibody 11D10 has the light and heavy chain variable region sequences contained in SEQ ID NO:2 and SEQ ID NO:4, respectively.

60. The composition of claim 38, further comprising an amount of the polynucleotide sufficient to elicit an anti-HMFG immunological response.

61. The composition of claim 41, further comprising an amount of the polynucleotide sufficient to elicit an anti-HMFG immunological response.

62. A polynucleotide according to claim 6, wherein the anti-HMFG immunological response comprises production of anti-HMFG antibody by the mammal.

63. A polynucleotide according to claim 6, wherein the anti-HMFG immunological response comprises production of anti-HMFG reactive T cells by the mammal.

64. A polynucleotide according to claim 6, encoding both an immunoglobulin variable region containing the three light chain CDRs of antibody 11D10 and an immunoglobulin variable region containing the three heavy chain CDRs of antibody 11D10.

65. A polynucleotide according to claim 64, wherein the variable regions are joined by a linked polypeptide of about 5 to 20 amino acids.

66. The immunogenic composition of claim 41, which is sterile.

70. A kit for eliciting an anti-HMFG immunological response in a mammal comprising the polynucleotide of claim 6 in suitable packaging.

71. A polynucleotide according to claim 64, wherein the light chain CDRs and the heavy chain CDRs are contained in SEQ ID NO:2 and SEQ ID NO:4, respectively.

72. A polynucleotide encoding an immunoglobulin variable region containing the three light chain CDRs in SEQ ID NO:2.

73. A polynucleotide encoding an immunoglobulin variable region containing the three heavy chain CDRs in SEQ ID NO:4.

74. A polynucleotide according to claim 72, wherein the variable region is contained in SEQ ID NO:2.

75. A polynucleotide according to claim 73, wherein the variable region is contained in SEQ ID NO:4.

76. A composition comprising the polynucleotide of any of claims 64, 65, 72, 73, 74, or 75 and a pharmaceutically acceptable excipient.

77. A host cell comprising the polynucleotide of any of claims 14, 15, 59, 71, 72, 73, 74, or 75, wherein the polynucleotide is a recombinant polynucleotide.

78. A polynucleotide according to any of claims 6-12, 14, 15, 59, 62-65, or 71-75, wherein the polynucleotide is a recombinant polynucleotide.

79. A composition according to any of claims 38, 41, 44, 45, 60, 61, 66, or 76, wherein the polynucleotide is a recombinant polynucleotide.

80. A kit according to any of claims 57, 58, or 70, wherein the polynucleotide is a recombinant polynucleotide.